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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

17 NATALIYA BORCHENKO, On
18 Behalf of Herself and All Others
19 Similarly Situated,

20 Plaintiff,

21 v.

22 L'ORÉAL USA, INC., a Delaware
23 corporation,

24 Defendant.

Case No.:

CLASS ACTION COMPLAINT FOR:

**VIOLATION OF THE UNFAIR
COMPETITION LAW, Business and
Professions Code §17200 *et seq.***

1 Plaintiff Nataliya Borchenko brings this action on behalf of herself and all
2 others similarly situated against Defendant L'Oréal USA, Inc., and states:

3 NATURE OF ACTION

4 1. Throughout the applicable limitations period, Defendant has
5 manufactured, marketed, sold, and distributed several skin care products under its
6 Revitalift® line. These products include: (1) Anti-Wrinkle + Firming Eye
7 Treatment; (2) Anti-Wrinkle + Firming Face & Neck Moisturizer; (3) Anti-
8 Wrinkle + Firming Day Moisturizer; (4) Anti-Wrinkle + Firming Night Cream
9 Moisturizer; (5) Cicacream; (6) Triple Power Intensive Skin Revitalizer Serum +
10 Moisturizer; (7) Triple Power Day Lotion Moisturizer; (8) Triple Power Deep-
11 Acting Moisturizer; (9) Triple Power Intensive Anti-Aging Overnight Mask; (10)
12 Triple Power Eye Treatment; (11) Triple Power Concentrated Serum Treatment;
13 (12) Triple Power Intensive Anti-Aging Day Cream Moisturizer; (13) Double
14 Lifting Face Treatment; (14) Double Lifting Eye Treatment; (15) Bright Reveal
15 Brightening Peel Pads; (16) Bright Reveal Brightening Day Moisturizer; and (17)
16 Bright Reveal Brightening Dual Overnight Moisturizer (the "Products").¹ The
17 Products are sold online and in virtually every major food, drug, and mass retail
18 outlet including, but not limited to Walgreens, CVS, Walmart, and Rite Aid. The
19 Products retail for approximately \$18.00-\$25.00.

20 2. On the front of each and every Product package, where consumers
21 cannot miss it, Defendant represents that the Products will reduce or repair
22 wrinkles. On the front of the Anti-Wrinkle + Firming Eye Treatment, Anti-Wrinkle
23 + Firming Face & Neck Moisturizer, Anti-Wrinkle + Firming Day Moisturizer,
24 Anti-Wrinkle + Firming Night Cream Moisturizer, Cicacream, Double Lifting Face
25 Treatment, Double Lifting Eye Treatment, and Brightening Dual Overnight
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27 ¹ Plaintiff reserves the right to add other products upon completion of discovery.
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1 Moisturizer, Defendant represents that the Products are “Anti-Wrinkle” products.
2 Similarly, Defendant represents on the front of the Triple Power Intensive Skin
3 Revitalizer Serum + Moisturizer that it will “Reduce Lines & Wrinkles” and
4 Defendant represents on the front of the Triple Power Intensive Anti-Aging
5 Overnight Mask, Triple Power Intensive Anti-Aging Day Cream Moisturizer,
6 Brightening Peel Pads, Brightening Day Moisturizer, and Brightening Dual
7 Overnight Moisturizer that the Products will “Reduce Wrinkles.” And, Defendant
8 represents on the front of the Triple Power Day Lotion Moisturizer, Triple Power
9 Deep-Acting Moisturizer, Triple Power Eye Treatment, and Triple Power
10 Concentrated Serum Treatment that the Products will “Repair Wrinkles”. The
11 Triple Power Day Lotion Moisturizer further represents that it “improve[s]” “coarse
12 wrinkles”, while the Double Lifting Eye Treatment represents that it “Helps to
13 reduce wrinkles”. These representations are collectively referred to as the “anti-
14 wrinkle representations”.

15 3. On the front of each and every Product package, where consumers
16 cannot miss it, Defendant also represents that the Products will “lift” the skin, by
17 branding them as “Revitalift” products. The front of the Triple Power Eye
18 Treatment further represents that the Product will “Lift Eye Area” and Defendant
19 also represents that the Product will “re-lift[]” skin and “visibly lift[] and firm[]
20 sagging skin around the eye area.” The front of the Double Lifting Face Treatment
21 further represents that it is an “Ultra Concentrated Lifting Gel”, while the Double
22 Lifting Eye Treatment represents that it is an “Upper Eye Lifting Gel” that will
23 “visibly lift the appearance of eyelids”. Similarly, the Triple Power Deep-Acting
24 Moisturizer and Triple Power Concentrated Serum Treatment further represent that
25 they “re-lift[]” skin. These representations are collectively referred to as the “lift
26 representations”.

27 4. On each and every Anti-Wrinkle + Firming Eye Treatment, Anti-
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1 Wrinkle + Firming Face & Neck Moisturizer, Anti-Wrinkle + Firming Day
2 Moisturizer, Anti-Wrinkle + Firming Night Cream Moisturizer, Cicacream, Triple
3 Power Intensive Skin Revitalizer Serum + Moisturizer, Triple Power Deep-Acting
4 Moisturizer, Triple Power Intensive Anti-Aging Overnight Mask, Triple Power
5 Concentrated Serum Treatment, Double Lifting Face Treatment, and Double Lifting
6 Eye Treatment product package, Defendant also represents that the Products will
7 “firm” or “redensify” the skin. Specifically, on the front of the Anti-Wrinkle +
8 Firming Eye Treatment, Anti-Wrinkle + Firming Face & Neck Moisturizer, Anti-
9 Wrinkle + Firming Day Moisturizer, and Anti-Wrinkle + Firming Night Cream
10 Moisturizer product packages, where consumers cannot miss it, Defendant
11 represents that the Products are “Firming” products that will “firm” skin. Similarly,
12 on the front of the Cicacream product, where consumers cannot miss it, Defendant
13 represents that the Product will “Firm Skin”. Defendant represents on the front of
14 the Triple Power Intensive Skin Revitalizer Serum + Moisturizer, Triple Power
15 Deep-Acting Moisturizer, Triple Power Intensive Anti-Aging Overnight Mask, and
16 Triple Power Intensive Anti-Aging Day Cream Moisturizer product packages,
17 where consumers cannot miss it, that the Products will “Re-Firm” the skin. And,
18 Defendant represents on the front of the Triple Power Deep Acting Moisturizer and
19 Triple Power Concentrated Serum Treatment product packages, where consumers
20 cannot miss it, that the Products will “redensify” the skin. The Anti-Wrinkle +
21 Firming Eye Treatment further represents that it provides “Firmer skin around the
22 eye area” and the Anti-Wrinkle + Firming Face & Neck Moisturizer represents that
23 in 4 weeks, “Firmness noticeably improves”. Similarly, the Triple Power Deep-
24 Acting Moisturizer represents that it “firms and tightens skin” and increases skin
25 elasticity, the Double Lifting Face Treatment represents that it “retighten[s] skin”,
26 and the Double Lifting Eye Treatment represents that it “helps to tighten skin above
27 the eyes”. These representations are collectively referred to as the “firming
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1 representations”.

2 5. Defendant further represents on the Anti-Wrinkle + Firming Eye
3 Treatment, Anti-Wrinkle + Firming Face & Neck Moisturizer, Anti-Wrinkle +
4 Firming Day Moisturizer, and Cicacream product labels that the Products will
5 “repair the skin barrier” and “strengthen[], and repair[] skin barrier” (collectively,
6 the “repair representations”).

7 6. The anti-wrinkle, lift, firming, and repair representations are
8 collectively referred to as the “skin structural representations” or “unlawful
9 representations”. By means of the skin structural representations, the Products
10 claim to affect the structure of consumers’ skin, making the Products “drugs” as
11 defined by California’s Sherman Food, Drug, and Cosmetic Law (“Sherman Law”).
12 Cal. Health & Safety Code § 109925(c).

13 7. Importantly, the “anti-wrinkle”, “lift”, and “firming” representations
14 on the front of the Product labels, to which all consumers are necessarily exposed,
15 as well as the repair representations, are stand-alone representations and are not
16 qualified by words such as “appearance” or “look” leading consumers to believe the
17 Products will affect the structure and function of their skin by lifting and firming
18 the skin, thus preventing new wrinkles from forming, and repairing the skin and
19 eliminating existing wrinkles as opposed to temporarily affecting the “appearance”
20 or “look” of the skin and wrinkles. Depending on the particular Product, Defendant
21 promises skin structural results in anywhere from 1 to 8 weeks.

22 8. Cosmetics cannot be marketed as skin structure altering drugs without
23 pre-approval from the FDA through the New Drug Application process unless they
24 conform to a “monograph” for a particular drug category, as established by the
25 FDA’s Over-the-Counter (OTC) Drug Review. Monographs identify approved
26 ingredients for specified uses generally recognized as safe and effective, and not
27 misbranded. U.S. FOOD & DRUG ADMINISTRATION, Is It a Cosmetic, a Drug,
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1 or Both? (Or Is It Soap?), *available at*
2 [https://www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm074201.](https://www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm074201.htm)
3 [htm](https://www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm074201.htm). Products containing active ingredients that are nonmonograph cannot be
4 marketed to the public without an approved New Drug Application that requires,
5 *inter alia*, that Defendant present evidence that the products are safe and effective
6 for their represented uses. U.S. FOOD & DRUG ADMINISTRATION, Over-the-
7 Counter (OTC) Drug Monograph Process, *available at*
8 [https://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedand](https://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/ucm317137.htm)
9 [approved/ucm317137.htm](https://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/ucm317137.htm).

10 9. The active ingredients in the Products do not conform to monographs
11 for wrinkle prevention, elimination, and reduction, or skin lifting, tightening,
12 firming, or repair. Defendant did not subject the Products to the FDA NDA process
13 and did not obtain pre-approval from the FDA to sell the Products with the skin
14 structural representations.

15 10. Thus, even if the skin structural representations are true – on which
16 Plaintiff takes no position – Defendant has been selling and marketing the Products
17 as drugs in violation of the “unlawful” prong of the UCL.

18 11. Plaintiff brings this action on behalf of herself and other similarly
19 situated consumers who purchased the Products seeking declaratory and injunctive
20 relief preventing the further unlawful sale of illegal and misbranded drugs until
21 Defendant obtains approved NDAs or removes the unlawful representations which
22 are injurious to the public at large and the removal or approval of which is
23 necessary to prevent future harm to the public at large. Plaintiff, on behalf of
24 herself and all other similarly situated consumers, also seeks a full refund of the
25 purchase price as the Products were being sold illegally as drugs. Alternatively,
26 Plaintiff seeks the premium paid for the Products over comparable L’Oreal and
27 competitor cosmetic products that do not make unlawful drug claims.
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JURISDICTION AND VENUE

12. This Court has jurisdiction pursuant to 28 U.S.C. § 1332(d)(2). The matter in controversy, exclusive of interest and costs, exceeds the sum or value of \$5,000,000 and is a class action in which there are in excess of 100 class members and some members of the Class are citizens of a state different from Defendant.

13. This Court has personal jurisdiction over Defendant because Defendant is authorized to conduct and do business in California, including this District. Defendant marketed, promoted, distributed, and sold the Products in California, and Defendant has sufficient minimum contacts with this State and/or sufficiently availed itself of the markets in this State through its promotion, sales, distribution, and marketing within this State, including this District, to render the exercise of jurisdiction by this Court permissible.

14. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(a) and (b) because a substantial part of the events giving rise to Plaintiff's claims occurred while she resided in this judicial district. Venue is also proper under 18 U.S.C. § 1965(a) because Defendant transacts substantial business in this District.

PARTIES

15. Plaintiff Nataliya Borchenko resides in Sherman Oaks, California. Throughout the relevant period, Plaintiff paid approximately \$20.00 to purchase Defendant's Anti-Wrinkle + Firming Eye Treatment; Anti-Wrinkle + Firming Night Cream Moisturizer; Triple Power Eye Treatment; and Double Lifting Eye Treatment Products from various stores in the Sherman Oaks area, including CVS, Rite-Aid, and Target. Plaintiff read the Product packages and she selected the premium-priced Products instead of less expensive comparable products based on the skin structural representations. As a result, Plaintiff suffered injury in fact and lost money. Now that Plaintiff knows the skin structural representations had not received the required FDA approval and the Products were illegally being

1 sold, Plaintiff has not purchased Defendant's Products again. However, Plaintiff
2 continues to desire to purchase skin creams that provide anti-wrinkle, lifting,
3 firming, and skin repair benefits. And, she would purchase Defendant's Products
4 again if the skin structural representations had received FDA approval and were
5 lawfully being made. Indeed, she regularly visits stores such as CVS, Rite-Aid,
6 and Target, where Defendant's Products are sold, but has been unable to
7 determine the lawfulness of the Product labels currently on the shelves. As long
8 as Defendant continues to make the skin structural representations as they
9 currently appear, then when presented with Defendant's packaging on any given
10 day, Plaintiff continues to have no way of determining whether the skin structural
11 representations have in fact been approved by the FDA.

12 16. Defendant L'Oréal USA, Inc. is a corporation organized and existing
13 under the laws of the State of Delaware. Defendant's headquarters is at 10
14 Hudson Yards, New York, NY, 10001. Defendant manufactures, distributes,
15 markets, and sells the Products to consumers throughout California.

16 **FACTUAL ALLEGATIONS**

17 17. Defendant's skin structural representations appear prominently and
18 conspicuously on each Product package as shown in Exhibit A, attached hereto.

19 18. Importantly, in addition to the skin structural representations,
20 Defendant features "Pro-Retinol" on the front of the Anti-Wrinkle + Firming Eye
21 Treatment, Anti-Wrinkle + Firming Face & Neck Moisturizer, Anti-Wrinkle +
22 Firming Day Moisturizer, Anti-Wrinkle + Firming Night Cream Moisturizer,
23 Double Lifting Face Treatment, and Double Lifting Eye Treatment product labels.
24 Certain products containing certain forms of retinol in certain strengths have been
25 approved by the FDA as drugs. Defendant's Products, however, have not been
26 approved by the FDA and the form of retinol in the Products does not conform to a
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1 monograph for the represented benefits. Featuring the “Pro-Retinol” in its
2 Products evidences Defendant’s intent to market its Products as drugs.

3 19. Further evidencing Defendant’s intent to market the Products as drugs
4 is that, unlike the “immediate”, and “overnight” cosmetic effects it promises, the
5 structural benefits require longer to take effect. For example, Defendant promises
6 that its Anti-Wrinkle + Firming Eye Treatment, Anti-Wrinkle + Firming Face &
7 Neck Moisturizer, and Anti-Wrinkle + Firming Day Moisturizer products will
8 “immediately” hydrate the skin (cosmetic claims), while the firming effects require
9 “1 week” or “4 weeks” to take effect. Similarly, the Anti-Wrinkle + Firming Night
10 Cream Moisturizer promises to make skin feel softer “overnight” (cosmetic claim),
11 while the wrinkle reduction and firming effects require “4 weeks”. And, the
12 Cicacream “immediately” makes skin feel “healthier, softer, smoother, and more
13 supple” and “noticeably more hydrated” (cosmetic claim), while the wrinkle
14 reduction and firming benefits take 2 or 4 weeks. The Triple Power Intensive Skin
15 Revitalizer Serum + Moisturizer the 2-in-1 Serum + Moisturizer provide moisture
16 and “softer, smoother and more supple” skin on “Day 1” (cosmetic claim), while
17 the firming and wrinkle reducing effects take 2 or 3 days. The Triple Power Day
18 Lotion Moisturizer “immediately” makes the skin feel soft (cosmetic claim), but the
19 wrinkle reduction effects take 2-8 weeks. The Triple Power Deep-Acting
20 Moisturizer “immediately” hydrates skin (cosmetic claim), but the firming and
21 elasticity benefits take “4 weeks”. The Triple Power Intensive Anti-Aging
22 Overnight Mask “immediately” makes skin feel “hydrated and supple” (cosmetic
23 claims), but the firming, tightening, lifting, and wrinkle reduction benefits take “4
24 weeks”. The Triple Power Eye Treatment “immediately” makes skin look brighter
25 (cosmetic claim), but the wrinkle reduction, firming, and lifting effects take “3
26 weeks”. The Triple Power Concentrated Serum Treatment “immediately” makes
27 complexion look more radiant (cosmetic claim), while the wrinkle reduction
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1 benefits take “4 weeks”. The Triple Power Intensive Anti-Aging Day Cream
2 Moisturizer “immediately” deeply hydrates the skin (cosmetic claim), but the
3 wrinkle reduction benefits take 1 week. The Brightening Peel Pads “immediately”
4 make skin “brighter” and “more radiant” (cosmetic claims), but the wrinkle
5 reduction benefits take “4 weeks”. The Brightening Day Moisturizer
6 “immediately” makes skin look brighter and more radiant (cosmetic claims), but the
7 wrinkle reduction effects take 1 week. Finally, the Brightening Dual Overnight
8 Moisturizer makes skin look “fresher” and “more radiant” and hydrates the skin,
9 making it feel “silky soft and more supple” the “next morning” (cosmetic claims),
10 but the wrinkle reduction benefits take 1 week.

11 20. Also evidencing Defendant’s intent to market the Products as drugs is
12 that Defendant sells other skin care products – including, for example, another less
13 expensive eye cream – that make only cosmetic claims.

14 21. Further evidencing Defendant’s intent to market the Products as drugs
15 is that Defendant encourages consumers to use the whole line of Revitalift
16 Products, stating in the “Directions” or “How to Use” section of some Product
17 labels: “[f]or best results, use in conjunction with other Revitalift products”, and
18 listing out specific Products to use in the “Your Recommended Regimen” section
19 of some Product labels.

20 22. An over-the-counter face cream or moisturizer can be a drug, a
21 cosmetic, or a combination of both. 21 U.S.C. § 359 (the categories of “drug” and
22 “cosmetic” are not mutually exclusive).

23 23. The federal Food, Drug, and Cosmetics Act (“FDCA”) (21 U.S.C.
24 §§301, *et seq.*) defines cosmetics as “articles intended to be rubbed, poured,
25 sprinkled, or sprayed on, introduced into, or otherwise applied to the human body ...
26 for cleansing, beautifying, promoting attractiveness, or altering the appearance.” 21
27 U.S.C. §321(i). The Products are cosmetics.

1 24. A cosmetic is **also** a drug if it is “intended to affect the structure or any
2 function of the body of man”. 21 U.S.C. § 321(g)(1).

3 25. California’s Sherman Law (California’s Health & Safety Code §§
4 109875, *et seq.*) parallels the FDCA in material part and adopts all nonprescription
5 drug regulations.

6 26. Like the FDCA, the Sherman Law defines a drug as “Any article other
7 than food, that is used or intended to affect the structure or any function of the body
8 of human beings.” Cal. Health & Safety Code § 109925(c).

9 27. Since at least 2012 and repeatedly thereafter, and as recently as
10 February 22, 2018, the FDA has made clear that any representation that a product
11 will prevent or remove wrinkles – such as the anti-wrinkle representations on the
12 Product labels – is a drug claim. Unlike purely cosmetic claims that promise to
13 alter the appearance of the user in a superficial way for a short period of time (e.g.,
14 hydrate, moisturize, improve appearance), drug claims – like the anti-wrinkle
15 representations – promise a material, lasting effect (e.g., “anti” meaning prevent
16 wrinkles as well as “reduce” existing wrinkles). As such, the FDA, in its industry
17 publications, explains that it has found that products “intended to affect the
18 structure or function of the body, such as the skin are drugs ... even if they affect
19 the appearance. So, if a product is intended, for example, *to remove wrinkles* or
20 increase the skin’s production of collagen, it’s a drug or a medical device.”
21 Wrinkle Treatments and Other Anti-aging Products, *available at*
22 <http://www.fda.gov/Cosmetics/ProductsIngredients/Products/ucm388826.htm>
23 (emphasis added). And, consistent with its position that anti-wrinkle claims are
24 drug claims, the FDA has sent numerous warning letters to product manufacturers
25 making such claims without FDA approval or pursuant to an established
26 monograph. *See, e.g.*, FDA’s May 26, 2017 letter to Star Health & Beauty, LLC,
27 *available* *at*

1 <https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2017/ucm563230>
2 .htm (“Stimulate ... reduction of deep wrinkles” and “reduces wrinkles” indicate
3 that products are drugs); FDA’s August 29, 2016 letter to ZO Skin Health Group,
4 LLC, *available at*
5 www.fda.gov/ICECI/EnforcementActions/WarningLetters/2016/ucm521019.htm
6 (“reduce wrinkle depth” indicates product is a drug); FDA’s April 14, 2016 letter to
7 Hollywood Skincare International, Inc. *available at*
8 www.fda.gov/ICECI/EnforcementActions/WarningLetters/2016/ucm504411.htm
9 (“removes wrinkles instantly” indicates product is a drug”); FDA’s October 5, 2012
10 letter to Bioque Technologies, *available at*
11 www.fda.gov/ICECI/EnforcementActions/WarningLetters/2012/ucm323767.htm
12 (“[A]chieve ... a 37% reduction in fine lines and wrinkles” and “repairing existing
13 wrinkles” indicate that products are drugs); FDA’s October 5, 2012 letter to Avon
14 Products, Inc., *available at*
15 www.fda.gov/ICECI/EnforcementActions/WarningLetters/2012/ucm323738.htm
16 (“help dramatically reverse visible wrinkles” indicates that product is a drug); and
17 FDA’s September 7, 2012 letter to Lancome, USA, *available at*
18 www.fda.gov/ICECI/EnforcementActions/WarningLetters/2012/ucm318809.htm
19 (“See significant deep wrinkle reduction in ... skin” indicates that product is a
20 drug).

21 28. The FDA has also warned that representations claiming that a product
22 will “lift” the skin – such as the lift representations on Defendant’s Products – are
23 drug claims. *See, e.g.,* FDA’s Feb 12, 2015 letter to Strivectin Operating
24 Company, *available at*
25 www.fda.gov/ICECI/EnforcementActions/WarningLetters/2015/ucm436692.htm
26 (“[n]ow even more tightening, lifting” and “providing noticeable lift and
27 resistance to gravity” indicate neck cream is a drug).

29. The FDA has also warned that representations claiming that a product will “tighten” or “firm” the skin – such as the firming representations on Defendant’s Products – are drug claims. *See, e.g.*, FDA’s Feb 12, 2015 letter to Strivectin Operating Company, *available at* www.fda.gov/ICECI/EnforcementActions/WarningLetters/2015/ucm436692.htm (“[n]ow even more tightening, lifting” indicates neck cream is a drug); FDA’s October 5, 2012 letter to Avon Products, Inc., *available at* www.fda.gov/ICECI/EnforcementActions/WarningLetters/2012/ucm323738.htm (“[H]elp tighten the connections between skin’s layers” indicates face cream is a drug); FDA’s October 5, 2012 letter to Bioque Technologies, *available at* www.fda.gov/ICECI/EnforcementActions/WarningLetters/2012/ucm323767.htm (“With regular use and in as little as four weeks, achieve a 42% increase in skin’s firmness” indicates skin cream is a drug).

30. And, since at least 2012 and repeatedly thereafter, and as recently as August 10, 2017, the FDA has made clear that any representation that a product will repair the skin – such as the repair representations on the Product labels – is a drug claim. *See, e.g.*, FDA’s June 15, 2017 letter to Soapwalla Inc., *available at* <https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2017/ucm564189.htm> (“repair[s] tissue damage” indicates product is a drug); FDA’s May 26, 2017 letter to Star Health & Beauty, LLC, *available at* <https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2017/ucm563230.htm> (representations that products “repair skin damage”, “help[] cells to renew themselves”, and contain “skin repairer” ingredients indicate products are drugs); FDA’s October 18, 2016 letter to PhytoCeuticals, Inc., *available at* www.fda.gov/ICECI/EnforcementActions/WarningLetters/2016/ucm525938.htm (representations that products “help with tissue repair”, “repair[] skin tissue”, “assist[] in skin regeneration”, and “accelerate[] cell renewal” indicate that

1 products are drugs); FDA's August 29, 2016 letter to ZO Skin Health Group, LLC,
2 *available* at
3 www.fda.gov/ICECI/EnforcementActions/WarningLetters/2016/ucm521019.htm
4 ("Helps support skin's natural mechanism to repair damage" indicates that
5 products are drugs); FDA's July 15, 2016 letter to Annmarie Gianni Skin Care,
6 *available* at
7 www.fda.gov/ICECI/EnforcementActions/WarningLetters/2016/ucm512070.htm (a
8 "new way for your skin to ... repair itself" indicates that product is a drug); FDA's
9 July 20, 2016 letter to Finally Pure, LLC, *available* at
10 www.fda.gov/ICECI/EnforcementActions/WarningLetters/2016/ucm515125.htm
11 ("Promotes skin repair and cell regeneration" indicates that product is a drug);
12 FDA's July 21, 2016 letter to La Bella Figura, LLC, *available* at
13 www.fda.gov/ICECI/EnforcementActions/WarningLetters/2016/ucm518518.htm
14 (aids in "repairing skin" indicates that product is a drug); FDA's December 3, 2015
15 letter to Dr. Brandt Skincare, *available* at
16 www.fda.gov/ICECI/EnforcementActions/WarningLetters/2015/ucm476560.htm
17 ("[R]epairs damaged skin" indicates that product is a drug); FDA's October 5, 2012
18 letter to Avon Products, Inc., *available* at
19 www.fda.gov/ICECI/EnforcementActions/WarningLetters/2012/ucm323738.htm
20 ("helps reactivate skin's repair process" indicate that product is a drug); FDA's
21 October 5, 2012 letter to Bioque Technologies, *available* at
22 www.fda.gov/ICECI/EnforcementActions/WarningLetters/2012/ucm323767.htm
23 ("Damaged skin cells repair themselves", "Fuel rebuilding of skin structure", and
24 "regeneration of skin cells" indicate products are drugs); FDA's September 21,
25 2012 letter to Andes Natural Skin Care, LLC, *available* at
26 www.fda.gov/ICECI/EnforcementActions/WarningLetters/2012/ucm321094.htm
27 ("repairs sun damaged tissue at the cellular level" and "repair of everyday and
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1 accumulated damage” indicate products are drugs); and FDA’s September 21, 2012
2 letter to Janson-Beckett, *available at*
3 www.fda.gov/ICECI/EnforcementActions/WarningLetters/2012/ucm321111.htm
4 (“helps repair aged skin”, “helps repair past damage”, and “helps to protect against
5 and repair ... skin damage” indicate products are drugs).

6 31. As the foregoing FDA publication and warning letters demonstrate, the
7 FDA requires manufacturers making identical or substantially similar structural
8 skin representations as Defendant to submit evidence of safety and effectiveness
9 and obtain an approved NDA prior to sale as required by 21 U.S.C. §§ 321(p) and
10 355(a). *See also* Cal. Health & Safety Code §§ 109980(a) and 111550.

11 32. Integral to the NDA process is demonstrating that the products are
12 generally recognized as safe for their intended uses – here, wrinkle prevention,
13 removal, and reduction, and skin lifting, tightening, firming, and repair. *See* FDA,
14 Over-the-Counter (OTC) Drug Monograph Process, *available at*
15 <http://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedand>
16 [approved/ucm317137.htm](http://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedand); FDA, How Drugs are Developed and Approved,
17 *available at*
18 www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandAp
19 [proved/ucm2007006.htm](http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandAp) (it is the responsibility of the company seeking to market
20 a drug to test it and submit evidence that it is safe and effective). By failing to have
21 its Products screened and approved for safety, Defendant is putting consumers at
22 risk of adverse reactions and other ill effects particularly since some of the Products
23 are to be applied to the sensitive eye area which is readily susceptible to infection.

24 33. By making the unlawful representations Defendant is also able to
25 charge a substantial premium for its Products over what it and its competitors
26 charge for similar cosmetic products which, for example, claim only to moisturize
27 and visibly improve the skin’s appearance or look and do not make the unlawful
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1 drug claims. Consequently, California consumers – like Plaintiff – are purchasing
 2 premium priced unlawful drugs not deemed to be safe or effective for preventing,
 3 removing, and reducing wrinkles, or skin lifting, tightening, firming, and repair as
 4 represented, rendering them valueless or, at a minimum, overpriced.

5 34. For all these reasons, Defendant should be enjoined from selling the
 6 Products with the unlawful skin structural representations until Defendant obtains
 7 an approved NDA or removes the drug claims which are injurious to the public at
 8 large and Plaintiff and the Class should be refunded their money or, at a minimum,
 9 the premium they paid to purchase the Products.

10 **CLASS DEFINITION AND ALLEGATIONS**

11 35. Plaintiff brings this action on behalf of herself and all other similarly
 12 situated consumers pursuant to Rule 23(a), (b)(2), and (b)(3) of the Federal Rules of
 13 Civil Procedure and seeks certification of the following Class:

14 All California consumers who within the applicable statute
 15 of limitations period until the date notice is disseminated,
 purchased the Products.

16 Excluded from this Class are Defendant and its officers,
 17 directors and employees, and those who purchased the
 Products for the purpose of resale.

18 36. **Numerosity.** The members of the Class are so numerous that joinder
 19 of all members of the Class is impracticable. Plaintiff is informed and believes that
 20 the proposed Class contains thousands of purchasers of the Products who have been
 21 damaged by Defendant's conduct as alleged herein. The precise number of Class
 22 members is unknown to Plaintiff.

23 37. **Existence and Predominance of Common Questions of Law and**
 24 **Fact.** This action involves common questions of law and fact, which predominate
 25 over any questions affecting individual Class members. These common legal and
 26 factual questions include, but are not limited to, the following:
 27
 28

1 (a) whether Defendant's alleged conduct is unlawful and constitutes
2 violations of the laws asserted; and

3 (b) whether Plaintiff and Class members are entitled to appropriate
4 remedies, including restitution and injunctive relief.

5 38. **Typicality.** Plaintiff's claims are typical of the claims of the members
6 of the Class because, *inter alia*, all Class members were injured through the
7 uniform misconduct described above. Plaintiff is also advancing the same claims
8 and legal theories on behalf of herself and all Class members.

9 39. **Adequacy of Representation.** Plaintiff will fairly and adequately
10 protect the interests of Class members. Plaintiff has retained counsel experienced
11 in complex consumer class action litigation, and Plaintiff intends to prosecute this
12 action vigorously. Plaintiff has no adverse or antagonistic interests to those of the
13 Class.

14 40. **Superiority.** A class action is superior to all other available means for
15 the fair and efficient adjudication of this controversy. The damages or other
16 financial detriment suffered by individual Class members is relatively small
17 compared to the burden and expense that would be entailed by individual litigation
18 of their claims against Defendant. It would thus be virtually impossible for
19 members of the Class, on an individual basis, to obtain effective redress for the
20 wrongs done to them. Furthermore, even if Class members could afford such
21 individualized litigation, the court system could not. Individualized litigation
22 would create the danger of inconsistent or contradictory judgments arising from the
23 same set of facts. Individualized litigation would also increase the delay and
24 expense to all parties and the court system from the issues raised by this action. By
25 contrast, the class action device provides the benefits of adjudication of these issues
26 in a single proceeding, economies of scale, and comprehensive supervision by a
27 single court, and presents no unusual management difficulties under the
28

1 circumstances here.

2 41. Plaintiff seeks injunctive and equitable relief on behalf of the entire
3 Class, on grounds generally applicable to the entire Class, to enjoin and prevent
4 Defendant from engaging in the acts described and requiring Defendant to provide
5 full restitution to Plaintiff and the Class members.

6 42. Unless a Class is certified, Defendant will retain monies received as a
7 result of its conduct that were taken from Plaintiff and Class members.

8 43. Unless an injunction is issued, Defendant will continue to commit the
9 violations alleged, and the members of the Class and the general public will
10 continue to purchase products not lawfully being sold and not recognized as safe.

11 **COUNT I**

12 **Violation of Business & Professions Code § 17200, *et seq.*** 13 **Unlawful Business Acts and Practices**

14 44. Plaintiff repeats and re-alleges the allegations contained in the
15 paragraphs above, as if fully set forth herein.

16 45. Plaintiff brings this claim individually and on behalf of the Class.

17 46. The Unfair Competition Law, Business & Professions Code § 17200,
18 *et seq.* (“UCL”), prohibits any “unlawful” business act or practice.

19 47. As alleged herein, Defendant engaged in and continues to engage in
20 illegal conduct by unlawfully making skin structural representations about the
21 Products, rendering them drugs, without monographs for the active ingredients and
22 without obtaining required FDA approval through the NDA process. Defendant
23 committed unlawful business practices by violating California’s Health & Safety
24 Code §§ 109875 *et seq.* and California’s Sherman Food, Drug and Cosmetic Law,
25 which materially adopts the relevant provisions of the Food Drug and Cosmetic
26 Act. Plaintiff reserves the right to allege other violations of law, which constitute
27 other unlawful business acts or practices. Such conduct is ongoing and continues to
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1 this date. Plaintiff and all Class members were exposed to the unlawful skin
2 structural representations at the point of purchase.

3 48. As alleged herein, Plaintiff has suffered injury in fact and lost money
4 or property as a result of Defendant's conduct because she saw and read the skin
5 structural representations, purchased the Anti-Wrinkle + Firming Eye Treatment,
6 Anti-Wrinkle + Firming Night Cream Moisturizer, Triple Power Eye Treatment,
7 and Double Lifting Eye Treatment Products based on the skin structural
8 representations, and she would not have done so but for Defendant's skin structural
9 representations which she now knows were unlawful. In addition, but for
10 Defendant's illegal conduct, the Products, including those that Plaintiff purchased,
11 would not have been on the market as anti-wrinkle, lifting, firming/tightening, and
12 repair products.

13 49. The NDA process is intended to ensure that if the consuming public
14 (e.g., Plaintiff) are sold a product that is a drug as defined under the FDA law and
15 regulations that is not generally recognized as safe and effective under an approved
16 monograph, it will have been put through the rigorous NDA process to ensure that
17 it is safe and effective.

18 50. The UCL unlawful prong is intended to hold defendants who engage in
19 unlawful conduct accountable for their violations by, among other things, paying
20 full compensation to consumers who have purchased such illegally sold products
21 that, by virtue of being banned from sale to the public, are valueless or, at a
22 minimum, overpriced.

23 51. Plaintiff and the Class members are entitled to the monies Defendant
24 wrongfully obtained in the amount of the full purchase price or, at a minimum, the
25 premium they paid for the Products.

26 52. Plaintiff, on behalf of herself and all similarly situated consumers,
27 seeks restitution of all money paid for Defendant's illegally sold Products or, at a
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1 minimum, the premium paid for the Products, consistent with Business &
2 Professions Code § 17203.

3 53. Plaintiff also seeks, on behalf of herself, all similarly situated
4 consumers and the public at large, declaratory relief and an injunction to enjoin and
5 prevent Defendant from engaging in the acts described, and all other relief this
6 Court deems appropriate, consistent with Business & Professions Code § 17203.

7 //

8 **PRAYER FOR RELIEF**

9 Wherefore, Plaintiff prays for a judgment:

- 10 A. Certifying the Class as requested herein;
11 B. Issuing an order declaring that Defendant is in violation of the UCL;
12 C. Enjoining Defendant's conduct;
13 D. Awarding appropriate restitution to Plaintiff and the proposed Class
14 members;
15 E. Awarding Plaintiff reasonable attorneys' fees and expenses pursuant to
16 Cal. C.C.P. § 1021.5; and
17 F. Awarding such other and further relief as this Court may deem just and
18 proper.

19
20 Dated: February 26, 2019

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